

00005.001298



PATENT APPLICATION

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

YUSHI KITAMURA, ET AL.

Application No.: 10/584,234

Filed: June 26, 2006

For: Hsp90 FAMILY PROTEIN  
INHIBITORS

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Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

September 26, 2006

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUBMISSION OF MISCELLANEOUS PCT FORMS

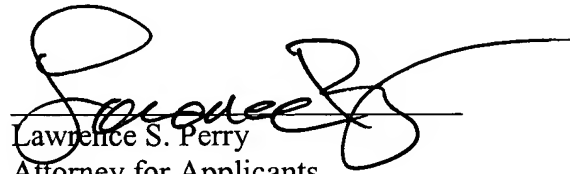
Sir:

Enclosed to complete the record and for the Examiner's convenience is Form PCT/IB/338, an English translation of the International Preliminary Report on Patentability (Form PCT/IB/373) and the Written Opinion of the International Searching Authority (Form PCT/ISA/237) in the above-identified application. The references discussed in the Written Opinion (or their patent family member equivalents) were all cited in Applicants' September 12, 2006 Information Disclosure Statement.

Entry hereof is earnestly solicited.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Lawrence S. Perry  
Attorney for Applicants  
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
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NY\_Main 593897\_1

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

KYOWA HAKKO KOGYO CO., LTD.  
6-1, Ohtemachi 1-chome, Chiyoda-ku,  
1008185  
JAPON

**RECEIVED**

SEP. - 7. 2006

**I.P. DEF**

Date of mailing (day/month/year)

31 August 2006 (31.08.2006)

Applicant's or agent's file reference  
1645**IMPORTANT NOTIFICATION**International application No.  
PCT/JP2004/019742International filing date (day/month/year)  
24 December 2004 (24.12.2004)

Applicant

KYOWA HAKKO KOGYO CO., LTD. et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1645	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/JP2004/019742	International filing date ( <i>day/month/year</i> ) 24 December 2004 (24.12.2004)	Priority date ( <i>day/month/year</i> ) 26 December 2003 (26.12.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> . 1(a).																								
2.	This REPORT consists of a total of 9 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. IV	Lack of unity of invention																							
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																							
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited																							
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																							
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 22 August 2006 (22.08.2006)
Facsimile No. +41 22 338 82 70	Authorized officer  <div style="text-align: right; font-weight: bold;">Yoshiko Kuwahara</div> e-mail: pt07@wipo.int

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**1645**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/019742**

International filing date (day/month/year)

**24.12.2004**

Priority date (day/month/year)

**26.12.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**KYOWA HAKKO KOGYO CO., LTD.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019742

Box No. I      Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language  
\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format  
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019742

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 26-33

because:

☒ the said international application, or the said claims Nos. 26-33

relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions in claims 26-33 relate to methods for treatment of the human body by therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 26-33

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No. .  
PCT/JP2004/019742

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	<u>4, 7, 8, 13, 19-21, 23-25, 36-41</u>	YES
	Claims	<u>1-3, 5, 6, 9-12, 14-18, 22, 34, 35</u>	NO
Inventive step (IS)	Claims	<u>4, 7, 8, 13, 19-21, 23-25, 36-41</u>	YES
	Claims	<u>1-3, 5, 6, 9-12, 14-18, 22, 34, 35</u>	NO
Industrial applicability (IA)	Claims	<u>1-25, 34-41</u>	YES
	Claims	_____	NO
<b>2. Citations and explanations:</b>			
(Documents cited in the ISR)			
Document 1: WO 2003/051805 A2 (WYETH) 26 June 2003			
Document 2: WO 2002/096901 A2 (WELLA AKTIENGESELLSCHAFT) 05 December 2002			
Document 3: JP 2000-287697 A (Shionogi & Co., Ltd.) 17 October 2000			
(Claims 4, 7, 8, 13, 19-21, 23-25, and 36-41)			
The inventions in claims 4, 7, 8, 13, 19-21, 23-25, and 36-41 are not described in any of the documents cited in the ISR, nor could they be easily conceived of from any documents.			
Thus, the inventions in claims 4, 7, 8, 13, 19-21, 23-25, and 36-41 appear to possess novelty and involve an inventive step.			
(Claims 1-3, 5, 6, 9-12, 14-18, 22, 34, and 35)			
(1) Document 1 describes compounds of formula I and pharmaceutically acceptable salts thereof (claim 1, claim 14), the use of these compounds in cancer treatment (claim 17), and compositions containing these compounds (claim 30).			
Document 1 does not describe compounds of formula I as Hsp 90 family protein inhibitors, but the Hsp 90 family protein inhibitors of the inventions in claims 1-3, 5, 6, 9-11, 22, 34, and 35 are used as antitumor agents, which is a use identical to compositions described in document 1, so the inventions in claims 1-3, 5, 6, 9-11, 22, 34, and 35 are the inventions described in document 1.			
Thus, the inventions in claims 1-3, 5, 6, 9-11, 22, 34, and 35 do not appear to possess novelty or involve an inventive step based on document 1.			

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019742

Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2005/000778 A1 [E, X]	06.01.2005	10.06.2004	27.06.2003
WO 2004/072051 A1 [E, X]	26.08.2004	09.02.2004	11.02.2003
WO 2004/081008 A1 [E, X]	23.09.2004	10.03.2004	14.03.2003
WO 2004/031159 A1 [E, X]	15.04.2004	24.09.2003	25.09.2002

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019742

Box No. VIII      Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The scope of the inventions in claims 1, 3-11, 22-25, 34, 36, 38, and 40 is ambiguous in terms of "prodrug" described in claims 1, 22-25, 34, 36, 38, and 40.

Claims 1-25 and 34-41 are matters relating to an Hsp family protein inhibitor represented by formula (I), a compound represented by formula (IA), or a medicine containing said compound as an active ingredient, but those disclosed in the sense of PCT Article 5 are merely those relating to an extremely small portion of the compounds, such as those in examples.

Consequently, claims 1-25 and 34-41 are considered to lack sufficient support by the description in the sense of PCT Article 6.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019742

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

(2) Document 2 describes compounds of formula (I) (claim 1).

Thus, the inventions in claims 12 and 14-17 do not appear to possess novelty or involve an inventive step based on document 2.

(3) Document 3 describes compounds of formula (I) and medical compositions containing said compounds (claim 1, claim 11).

Thus, the inventions in claims 12, 15-18, and 22 do not appear to possess novelty or involve an inventive step based on document 3.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019742

Supplemental Box

(Continuation of International Patent Classification (IPC))

Int.cl<sup>7</sup> A61K31/496, 31/4402, 31/4409, 31/4184, 31/472, 31/341, 31/343, 31/4178,  
31/4025, 31/4184, 31/426, 31/351, 31/36, 31/357, A61P43/00, 35/00, C07C215/46,  
251/48, 235/34, 235/36, 309/65, 307/02, 311/08, 311/21, 69/732, 59/56, 39/367,  
43/178, 43/23, 49/245, 69/734, 49/84, C07D263/16, 271/113, 263/24, 303/26,  
333/16, 405/12, 295/14, 295/18, 213/40, 213/36, 213/85, 213/30, 231/56, 211/02,  
207/18, 217/06, 307/12, 307/68, 307/48, 307/52, 307/54, 307/91, 263/32, 263/34,  
235/18, 277/24, 309/06, 317/18, 317/54, C07H15/18,